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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,273	08/27/2003	Jian Chen	D0073 CNT	7258
23914	7590	12/22/2004	EXAMINER SWOPE, SHERIDAN	
STEPHEN B. DAVIS BRISTOL-MYERS SQUIBB COMPANY PATENT DEPARTMENT P O BOX 4000 PRINCETON, NJ 08543-4000			ART UNIT 1652	PAPER NUMBER

DATE MAILED: 12/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/649,273	CHEN ET AL.	
	Examiner	Art Unit	
	Sheridan L. Swope	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 1-24 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, 8, 9, and 14-19, drawn to a nucleic acid molecule, vectors, host cells, and methods of making the encoded protein, classified in class 435, subclass 226.
- II. Claims 5, 6, 10, and 20, drawn to a protease polypeptide, classified in class 435, subclass 226.
- III. Claim 7, drawn to an antibody, classified in class 530, subclass 389.1.
- IV. Claims 11 and 21-26, drawn to a method of treatment with a polypeptide, classified in class 424, subclass 94.65.
- V. Claim 12, drawn to a method of diagnosis by assaying mutation of a polynucleotide, classified in class 435, subclass 91.2.
- VI. Claim 13, drawn to a method of diagnosis by assaying polypeptide levels, classified in class 435, subclass 23.
- VII. Claim 27, drawn to a computer, classified in class 702, subclass 19.
- VIII. Claims 28 and 31, drawn to a method of designing protease mutants, classified in class D14, subclass 485.
- IX. Claims 29, 30, and 32, drawn to a method of designing modulators, classified in class D14, subclass 485.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects

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(MPEP § 806.04, MPEP § 808.01). Also, product and process inventions are distinct if any of the following can be shown: (1) that the process as claimed can be used to make another and materially different product, (2) that the product claimed can be used in a materially different process of using that product, or (3) that the product claimed can be made by another and materially different process (MPEP § 806.05(h)). These inventions are different or distinct for the following reasons.

The polynucleotide of Invention I is related to the polypeptide of Invention II by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the polypeptide in host cells, as recited in Claim 9. Although the DNA molecule and polypeptide are related since the DNA encodes the specifically claimed polypeptide, they are distinct inventions because they are physically and functionally distinct chemical entities, and the polypeptide product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the polypeptide, such as in a nucleic acid hybridization assay. The search of Invention I would not encompass a search for Invention II, which would include searching the prior art for teachings of the purified polypeptide. Conversely, a search for Invention II, class 435, subclass 226, would not encompass a search for Invention I, which would also include searching class 435, subclasses 69.1, 252.3, and 320.1 as well as class 536, subclass 23.2. Thus, a search of either Invention I or II would not encompass a search for the other invention and searching both inventions would be a burden on the Office.

Inventions I, III, and VII are unrelated because the products of Inventions I, III, and VII are physically and functionally distinct chemical entities. As reflected in the distinct

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classifications, a search for any one invention would not encompass a search for any other invention and searching all inventions, or any combination, would be a burden on the Office.

Inventions II and VII are unrelated because the products of Inventions II and VI are physically and functionally distinct chemical entities. As reflected in the distinct classifications, a search for any one invention would not encompass a search for the other invention and searching both inventions would be a burden on the Office.

The proteins of Invention II are related to the antibodies of Invention III by virtue of being the cognate antigen necessary for the production of antibodies. Although the protein and antibody are related, due to the necessary steric complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities and because the protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right or in assays for the identification of agonists or antagonists of the enzyme. As reflected in the distinct classifications, a search for any one invention would not encompass a search for the other invention and searching both inventions would be a burden on the Office.

Inventions IV-VI, VIII, and IX are independent because the methods of Inventions IV-VI, VIII, and IX comprise different steps, utilize different products and/or produce different results. A search for one invention would not encompass a search for the other inventions. Although Inventions VIII and IX have the same major classification, a search for one of said methods would not encompass a search for the other method because each method uses different step and products and produce different results. Inventions IV-VI each have a different classification. Thus, the search for any one invention would not encompass the search for any

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other invention and searching all of Inventions IV-VI, VIII, and IX, or any combination thereof, would be a burden on the Office.

Invention IV is unrelated to Inventions I, III, and VII because, the method of Invention IV can neither use the products of Inventions I, III, and VII nor be used to make said products. As indicated by the different classifications, a search for Invention IV would not overlap a search for any of Inventions I, III, or VII and searching Invention IV with any of Inventions I, III, or VII would be a burden on the Office.

Invention V is unrelated to Inventions II, III, and VII because the method of Invention V can neither use the products of Inventions II, III, and VII nor be used to make said products. As indicated by the different classifications, a search for Invention V would not overlap a search for any of Inventions II, III, or VII and searching Invention V with either Invention II, III, or VII would be a burden on the Office.

Invention VI is unrelated to Inventions I and VII because the method of Invention VI can neither use the products of Inventions I and VII nor be used to make said products. As indicated by the different classifications, a search for Invention VI would not overlap a search for Invention I or VII and searching Invention VI with either Invention I or VII would be a burden on the Office.

Inventions VIII and IX are unrelated to Inventions I-III because the methods of Inventions VIII and IX can neither use the products of Inventions I-III nor be used to make said products. As indicated by the different classifications, a search for Invention VIII or IX would not overlap a search for any of Inventions I-III and searching Invention VIII or IX with any of Inventions I-III would be a burden on the Office.

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The methods of Invention IV are related to the polypeptide of Invention II as a product and process of using. However, the inventions are distinct because the polypeptide can also be used for production of an antibody or in assays for the identification of agonists or antagonists of the enzyme. As reflected in the distinct classifications, a search for one invention would not encompass a search for the other invention and searching both inventions would be a burden on the Office.

The methods of Invention V are related to the nucleic acid molecule of Invention I as a product and process of using. However, the inventions are distinct because the nucleic acid molecule can also be used for production of the encoded polypeptide. As reflected in the distinct classifications, a search for any one invention would not encompass a search for the other invention and searching both inventions would be a burden on the Office.

The methods of Invention VI are related to the polypeptide and antibody of Inventions II and III, respectively, as a product and process of using. However, the inventions are distinct because the polypeptide can also be used for production of the antibody, while the antibody can also be used for purification of the polypeptide. As reflected in the distinct classifications, a search for Invention VI would not encompass a search for Invention II or III and searching Invention VI with Invention II or III would be a burden on the Office.

The methods of Inventions VIII and IX are related to the computer of Invention VII as a product and process of using. However, the inventions are distinct because the computer can also be used for producing three-dimensional representations of proteins other than Protease-42. As reflected in the distinct classifications, a search for Invention VII would not encompass a

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search for Invention VIII or IX and Invention VII with Invention VIII or IX would be a burden on the Office.

These inventions are distinct for the reasons given above and have acquired a separate status in the art due to their recognized divergent subject matter, as shown by their different classification. Furthermore, as explained above, searching more than one invention would be a burden on the Office. Therefore, restriction for examination purposes, as indicated, is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Restriction between product and process claims has been required. Where Applicant elects claims directed to a product, and the product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. 821.04, *In re Ochiai*, and *In re Brouwer*). Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right, if the amendment is presented prior to final rejection or allowance, whichever is earlier. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. To be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943.

The examiner can normally be reached on M-F; 9:30-6 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Sheridan L. Swope, Ph.D.


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